

Amendments to the Claims:

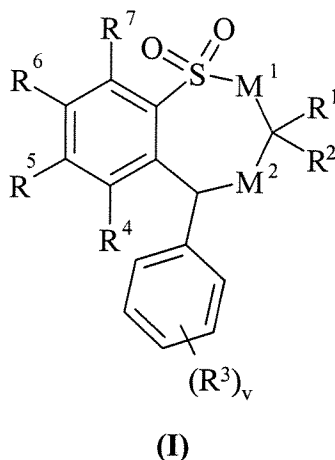
This listing of claims will replace all prior versions and listing of claims in the application.

Please amend claims 1 to 12, 13, 17 and 18 as indicated.

Please cancel claims 14 to 16 and 19 to 25 without prejudice or disclaimer.

Listing of the Claims:

Claim 1 (currently amended): A compound of formula (I):



wherein

M^1 is $-CH_2-$ or $-NR^{21}-$;

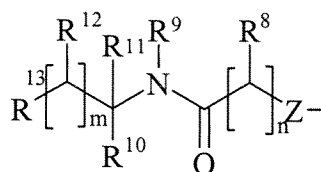
M^2 is $-CR^{22}R^{23}-$ or $-NR^{24}-$; provided that if M^1 is $-NR^{21}-$, M^2 is $-CR^{22}R^{23}-$;

one ~~One~~ of R^1 and R^2 is ~~are~~ selected from hydrogen, C_{1-6} alkyl or C_{2-6} alkenyl and the other is selected from C_{1-6} alkyl or C_{2-6} alkenyl;

R^3 is selected from halo, nitro, cyano, hydroxy, amino, carboxy, carbamoyl, mercapto, sulphamoyl, C_{1-6} alkyl, C_{2-6} alkenyl, C_{2-6} alkynyl, C_{1-6} alkoxy, C_{1-6} alkanoyl, C_{1-6} alkanoyloxy, N -(C_{1-6} alkyl)amino, N,N -(C_{1-6} alkyl)₂amino, C_{1-6} alkanoylamino, N -(C_{1-6} alkyl)carbamoyl, N,N -(C_{1-6} alkyl)₂carbamoyl, C_{1-6} alkylS(O)_a wherein a is 0 to 2, C_{1-6} alkoxycarbonyl, N -(C_{1-6} alkyl)sulphamoyl and N,N -(C_{1-6} alkyl)₂sulphamoyl;

v is 0-5;

one of R^5 and R^6 is a group of formula (IA):



(IA)

R⁴ and **R⁷** and the other of **R⁵** and **R⁶** are independently selected from hydrogen, halo, nitro, cyano, hydroxy, amino, carboxy, carbamoyl, mercapto, sulphamoyl, C₁₋₄alkyl, C₂₋₄alkenyl, C₂₋₄alkynyl, C₁₋₄alkoxy, C₁₋₄alkanoyl, C₁₋₄alkanoyloxy, *N*-(C₁₋₄alkyl)amino, *N,N*-(C₁₋₄alkyl)₂amino, C₁₋₄alkanoylamino, *N*-(C₁₋₄alkyl)carbamoyl, *N,N*-(C₁₋₄alkyl)₂carbamoyl, C₁₋₄alkylS(O)_a wherein a is 0 to 2, C₁₋₄alkoxycarbonyl, *N*-(C₁₋₄alkyl)sulphamoyl and *N,N*-(C₁₋₄alkyl)₂sulphamoyl; wherein **R⁴** and **R⁷** and the other of **R⁵** and **R⁶** may be optionally substituted on carbon by one or more **R²⁵**;

Z is -O-, -N(**R^a**)-, -S(O)_b- or -CH(**R^a**)-; wherein **R^a** is hydrogen or C₁₋₆alkyl and b is 0-2;

R⁸ is hydrogen, C₁₋₄alkyl, carbocyclyl or heterocyclyl; wherein **R⁸** may be optionally substituted on carbon by one or more substituents selected from **R²⁶**; and wherein if said heterocyclyl contains an -NH- group, that nitrogen may be optionally substituted by a group selected from **R²⁷**;

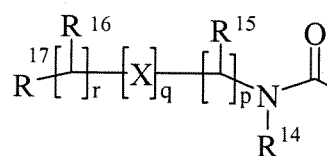
R⁹ is hydrogen or C₁₋₄alkyl;

R¹⁰ and **R¹¹** are independently selected from hydrogen, C₁₋₄alkyl, carbocyclyl or heterocyclyl; or **R¹⁰** and **R¹¹** together form C₂₋₆alkylene; wherein **R¹⁰** and **R¹¹** or **R¹⁰** and **R¹¹** together may be independently optionally substituted on carbon by one or more substituents selected from **R²⁸**; and wherein if said heterocyclyl contains an -NH- moiety, that nitrogen may be optionally substituted by one or more **R²⁹**;

R¹² is hydrogen, C₁₋₄alkyl, carbocyclyl or heterocyclyl; wherein **R¹²** may be optionally substituted on carbon by one or more substituents selected from **R³⁰**; and wherein if said heterocyclyl contains an -NH- moiety, that nitrogen may be optionally substituted by one or more **R³¹**;

R¹³ is hydrogen, halo, nitro, cyano, hydroxy, amino, carbamoyl, mercapto, sulphamoyl, hydroxyaminocarbonyl, C₁₋₁₀alkyl, C₂₋₁₀alkenyl, C₂₋₁₀alkynyl, C₁₋₁₀alkoxy,

C₁₋₁₀alkoxycarbonyl, C₁₋₁₀alkanoyl, C₁₋₁₀alkanoyloxy, *N*-(C₁₋₁₀alkyl)amino, *N,N*-(C₁₋₁₀alkyl)₂amino, *N,N,N*-(C₁₋₁₀alkyl)₃ammonio, C₁₋₁₀alkanoylamino, *N*-(C₁₋₁₀alkyl)carbamoyl, *N,N*-(C₁₋₁₀alkyl)₂carbamoyl, C₁₋₁₀alkylS(O)_a wherein a is 0 to 2, *N*-(C₁₋₁₀alkyl)sulphamoyl, *N,N*-(C₁₋₁₀alkyl)₂sulphamoyl, *N*-(C₁₋₁₀alkyl)sulphamoylamino, *N,N*-(C₁₋₁₀alkyl)₂sulphamoylamino, C₁₋₁₀alkoxycarbonylamino, carbocyclyl, carbocyclylC₁₋₁₀alkyl, heterocyclic group, heterocyclylC₁₋₁₀alkyl, carbocyclyl-(C₁₋₁₀alkylene)_e-R³²-(C₁₋₁₀alkylene)_f or heterocyclyl-(C₁₋₁₀alkylene)_g-R³³-(C₁₋₁₀alkylene)_h; wherein R¹³ may be optionally substituted on carbon by one or more substituents selected from R³⁶; and wherein if said heterocyclyl contains an -NH- group, that nitrogen may be optionally substituted by a group selected from R³⁷; or R¹³ is a group of formula **(IB)**:



(IB)

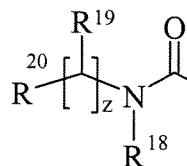
wherein:

X is -N(R³⁸)-, -N(R³⁸)C(O)-, -O-, and -S(O)_a-; wherein a is 0-2 and R³⁸ is hydrogen or C₁₋₄alkyl;

R¹⁴ is hydrogen or C₁₋₄alkyl;

R¹⁵ and R¹⁶ are independently selected from hydrogen, halo, nitro, cyano, hydroxy, amino, carbamoyl, mercapto, sulphamoyl, C₁₋₆alkyl, C₂₋₆alkenyl, C₂₋₆alkynyl, C₁₋₆alkoxy, C₁₋₆alkanoyl, C₁₋₆alkanoyloxy, *N*-(C₁₋₆alkyl)amino, *N,N*-(C₁₋₆alkyl)₂amino, C₁₋₆alkanoylamino, *N*-(C₁₋₆alkyl)carbamoyl, *N,N*-(C₁₋₆alkyl)₂carbamoyl, C₁₋₆alkylS(O)_a wherein a is 0 to 2, C₁₋₆alkoxycarbonyl, *N*-(C₁₋₆alkyl)sulphamoyl, *N,N*-(C₁₋₆alkyl)₂sulphamoyl, carbocyclyl or heterocyclic group; wherein R¹⁵ and R¹⁶ may be independently optionally substituted on carbon by one or more substituents selected from R⁴¹; and wherein if said heterocyclyl contains an -NH- group, that nitrogen may be optionally substituted by a group selected from R⁴²;

R¹⁷ is selected from hydrogen, halo, nitro, cyano, hydroxy, amino, carbamoyl, mercapto, sulphamoyl, hydroxyaminocarbonyl, C₁₋₁₀alkyl, C₂₋₁₀alkenyl, C₂₋₁₀alkynyl, C₁₋₁₀alkoxy, C₁₋₁₀alkanoyl, C₁₋₁₀alkanoyloxy, *N*-(C₁₋₁₀alkyl)amino, *N,N*-(C₁₋₁₀alkyl)₂amino, C₁₋₁₀alkanoylamino, *N*-(C₁₋₁₀alkyl)carbamoyl, C₁₋₁₀alkoxycarbonyl, *N,N*-(C₁₋₁₀alkyl)₂carbamoyl, C₁₋₁₀alkylS(O)_a wherein a is 0 to 2, *N*-(C₁₋₁₀alkyl)sulphamoyl, *N,N*-(C₁₋₁₀alkyl)₂sulphamoyl, *N*-(C₁₋₁₀alkyl)sulphamoylamino, *N,N*-(C₁₋₁₀alkyl)₂sulphamoylamino, carbocyclyl, carbocyclylC₁₋₁₀alkyl, heterocyclic group, heterocyclylC₁₋₁₀alkyl, carbocyclyl-(C₁₋₁₀alkylene)_e-R⁴³-(C₁₋₁₀alkylene)_f- or heterocyclyl-(C₁₋₁₀alkylene)_g-R⁴⁴-(C₁₋₁₀alkylene)_h-; wherein R¹⁷ may be optionally substituted on carbon by one or more substituents selected from R⁴⁷; and wherein if said heterocyclyl contains an -NH- group, that nitrogen may be optionally substituted by a group selected from R⁴⁸; or R¹⁷ is a group of formula (IC):



(IC)

wherein:

R¹⁸ is selected from hydrogen or C₁₋₄alkyl;

R¹⁹ is selected from hydrogen, halo, nitro, cyano, hydroxy, amino, carbamoyl, mercapto, sulphamoyl, C₁₋₆alkyl, C₂₋₆alkenyl, C₂₋₆alkynyl, C₁₋₆alkoxy, C₁₋₆alkanoyl, C₁₋₆alkanoyloxy, *N*-(C₁₋₆alkyl)amino, *N,N*-(C₁₋₆alkyl)₂amino, C₁₋₆alkanoylamino, *N*-(C₁₋₆alkyl)carbamoyl, *N,N*-(C₁₋₆alkyl)₂carbamoyl, C₁₋₆alkylS(O)_a wherein a is 0 to 2, C₁₋₆alkoxycarbonyl, *N*-(C₁₋₆alkyl)sulphamoyl, *N,N*-(C₁₋₆alkyl)₂sulphamoyl, carbocyclyl or heterocyclic group; where R¹⁹ may be independently optionally substituted on carbon by one or more substituents selected from R⁵¹; and wherein if said heterocyclyl contains an -NH- group, that nitrogen may be optionally substituted by a group selected from R⁵²;

R²⁰ is selected from halo, nitro, cyano, hydroxy, amino, carbamoyl, mercapto, sulphamoyl, hydroxyaminocarbonyl, C₁₋₁₀alkyl, C₂₋₁₀alkenyl, C₂₋₁₀alkynyl, C₁₋₁₀alkoxy,

C₁₋₁₀alkoxycarbonyl, C₁₋₁₀alkanoyl, C₁₋₁₀alkanoyloxy, *N*-(C₁₋₁₀alkyl)amino, *N,N*-(C₁₋₁₀alkyl)₂amino, *N,N,N*-(C₁₋₁₀alkyl)₃ammonio, C₁₋₁₀alkanoylamino, *N*-(C₁₋₁₀alkyl)carbamoyl, *N,N*-(C₁₋₁₀alkyl)₂carbamoyl, C₁₋₁₀alkylS(O)_a wherein a is 0 to 2, *N*-(C₁₋₁₀alkyl)sulphamoyl, *N,N*-(C₁₋₁₀alkyl)₂sulphamoyl, *N*-(C₁₋₁₀alkyl)sulphamoylamino, *N,N*-(C₁₋₁₀alkyl)₂sulphamoylamino, C₁₋₁₀alkoxycarbonylamino, carbocyclyl, carbocyclylC₁₋₁₀alkyl, heterocyclic group, heterocyclylC₁₋₁₀alkyl, carbocyclyl-(C₁₋₁₀alkylene)_e-R⁵³-(C₁₋₁₀alkylene)_f- or heterocyclyl-(C₁₋₁₀alkylene)_g-R⁵⁴-(C₁₋₁₀alkylene)_h-; wherein R²⁰ may be independently optionally substituted on carbon by one or more R⁵⁷; and wherein if said heterocyclyl contains an -NH- group, that nitrogen may be optionally substituted by a group selected from R⁵⁸;

p is 1-3; wherein the values of R¹⁵ may be the same or different;

q is 0-1;

r is 0-3; wherein the values of R¹⁶ may be the same or different;

m is 0-2; wherein the values of R¹² may be the same or different;

n is 1-2; wherein the values of R⁸ may be the same or different;

z is 0-3; wherein the values of R¹⁹ may be the same or different;

R²¹ is selected from hydrogen or C₁₋₆alkyl;

R²² and **R²³** are independently selected from hydrogen, hydroxy, amino, mercapto, C₁₋₆alkyl, C₁₋₆alkoxy, *N*-(C₁₋₆alkyl)amino, *N,N*-(C₁₋₆alkyl)₂amino, C₁₋₆alkylS(O)_a wherein a is 0 to 2;

R²⁴ is selected from hydrogen, hydroxy, C₁₋₆alkyl, C₁₋₄alkoxy and C₁₋₆alkanoyloxy;

R²⁵ is selected from halo, nitro, cyano, hydroxy, amino, carboxy, carbamoyl, mercapto, sulphamoyl, C₁₋₄alkyl, C₂₋₄alkenyl, C₂₋₄alkynyl, C₁₋₄alkoxy, C₁₋₄alkanoyl, C₁₋₄alkanoyloxy, *N*-(C₁₋₄alkyl)amino, *N,N*-(C₁₋₄alkyl)₂amino, C₁₋₄alkanoylamino, *N*-(C₁₋₄alkyl)carbamoyl, *N,N*-(C₁₋₄alkyl)₂carbamoyl, C₁₋₄alkylS(O)_a wherein a is 0 to 2, C₁₋₄alkoxycarbonyl, *N*-(C₁₋₄alkyl)sulphamoyl and *N,N*-(C₁₋₄alkyl)₂sulphamoyl; wherein R²⁵, may be independently optionally substituted on carbon by one or more R⁶⁷;

R²⁶, **R²⁸**, **R³⁰**, **R³⁶**, **R⁴¹**, **R⁴⁷**, **R⁵¹** and **R⁵⁷** are independently selected from halo, nitro, cyano, hydroxy, amino, carbamoyl, mercapto, sulphamoyl, hydroxyaminocarbonyl, C₁₋₁₀alkyl, C₂₋₁₀alkenyl, C₂₋₁₀alkynyl, C₁₋₁₀alkoxy, C₁₋₁₀alkanoyl, C₁₋₁₀alkanoyloxy, C₁₋₁₀alkoxycarbonyl,

N-(C₁₋₁₀alkyl)amino, *N,N*-(C₁₋₁₀alkyl)₂amino, *N,N,N*-(C₁₋₁₀alkyl)₃ammonio, C₁₋₁₀alkanoylamino, *N*-(C₁₋₁₀alkyl)carbamoyl, *N,N*-(C₁₋₁₀alkyl)₂carbamoyl, C₁₋₁₀alkylS(O)_a wherein a is 0 to 2, *N*-(C₁₋₁₀alkyl)sulphamoyl, *N,N*-(C₁₋₁₀alkyl)₂sulphamoyl, *N*-(C₁₋₁₀alkyl)sulphamoylamino, *N,N*-(C₁₋₁₀alkyl)₂sulphamoylamino, C₁₋₁₀alkoxycarbonylamino, carbocyclyl, carbocyclylC₁₋₁₀alkyl, heterocyclic group, heterocyclylC₁₋₁₀alkyl, carbocyclyl-(C₁₋₁₀alkylene)_e-R⁵⁹-(C₁₋₁₀alkylene)_f- heterocyclyl-(C₁₋₁₀alkylene)_g-R⁶⁰-(C₁₋₁₀alkylene)_h-; wherein R²⁶, R²⁸, R³⁰, R³⁶, R⁴¹, R⁴⁷, R⁵¹ and R⁵⁷ may be independently optionally substituted on carbon by one or more R⁶³; and wherein if said heterocyclyl contains an -NH- group, that nitrogen may be optionally substituted by a group selected from R⁶⁴;

R²⁷, R²⁹, R³¹, R³⁷, R⁴², R⁴⁸, R⁵², R⁵⁸ and R⁶⁴ are independently selected from C₁₋₆alkyl, C₁₋₆alkanoyl, C₁₋₆alkylsulphonyl, sulphamoyl, *N*-(C₁₋₆alkyl)sulphamoyl, *N,N*-(C₁₋₆alkyl)₂sulphamoyl, C₁₋₆alkoxycarbonyl, carbamoyl, *N*-(C₁₋₆alkyl)carbamoyl, *N,N*-(C₁₋₆alkyl)₂carbamoyl, benzyl, phenethyl, benzoyl, phenylsulphonyl and phenyl;

R³², R³³, R⁴³, R⁴⁴, R⁵³, R⁵⁴, R⁵⁹ and R⁶⁰ are independently selected from -O-, -NR⁶⁵-, -S(O)_x-, -NR⁶⁵C(O)NR⁶⁶-, -NR⁶⁵C(S)NR⁶⁶-, -OC(O)N=C-, -NR⁶⁵C(O)- or -C(O)NR⁶⁵-; wherein R⁶⁵ and R⁶⁶ are independently selected from hydrogen or C₁₋₆alkyl, and x is 0-2;

R⁶³ and R⁶⁷ are independently selected from halo, hydroxy, cyano, carbamoyl, ureido, amino, nitro, carbamoyl, mercapto, sulphamoyl, trifluoromethyl, trifluoromethoxy, methyl, ethyl, methoxy, ethoxy, vinyl, allyl, ethynyl, methoxycarbonyl, formyl, acetyl, formamido, acetylamino, acetoxymethyl, methylamino, dimethylamino, *N*-methylcarbamoyl, *N,N*-dimethylcarbamoyl, methylthio, methylsulphinyl, mesyl, *N*-methylsulphamoyl and *N,N*-dimethylsulphamoyl; and

e, f, g and h are independently selected from 0-2;

or a pharmaceutically acceptable salt, ~~solvate, solvate of such a salt~~ or a prodrug thereof.

Claim 2 (currently amended): A compound of formula (I) according to claim 1 wherein M¹ is -CH₂- and M² is -CR²²R²³-; or a pharmaceutically acceptable salt, ~~solvate, solvate of such a salt~~ or a prodrug thereof.

Claim 3 (currently amended): A compound of formula (I) according to claim 1 wherein M¹ is -CH₂- and M² is -NR²⁴-; or a pharmaceutically acceptable salt, ~~solvate, solvate of such a salt or a~~ prodrug thereof.

Claim 4 (currently amended): A compound of formula (I) according to claim 1 ~~or 2~~ wherein R²² and R²³ are independently selected from hydrogen and hydroxy; or a pharmaceutically acceptable salt, ~~solvate, solvate of such a salt or a~~ prodrug thereof.

Claim 5 (currently amended): A compound of formula (I) according to claim 1 ~~or 3~~ wherein R²⁴ is hydrogen; or a pharmaceutically acceptable salt, ~~solvate, solvate of such a salt or a~~ prodrug thereof.

Claim 6 (currently amended): A compound of formula (I) according to claim 1 ~~any one of~~ ~~claims 1-5~~ wherein R¹ and R² are C₁₋₄alkyl; or a pharmaceutically acceptable salt, ~~solvate, solvate of such a salt or a~~ prodrug thereof.

Claim 7 (currently amended): A compound of formula (I) according to claim 1 ~~any one of~~ ~~claims 1-6~~ wherein v is 0; or a pharmaceutically acceptable salt, ~~solvate, solvate of such a salt or~~ a prodrug thereof.

Claim 8 (currently amended): A compound of formula (I) according to claim 1 ~~any one of~~ ~~claims 1-7~~ wherein R⁴ and R⁷ are hydrogen; or a pharmaceutically acceptable salt, ~~solvate, solvate of such a salt or a~~ prodrug thereof.

Claim 9 (currently amended): A compound of formula (I) according to claim 1 ~~any one of~~ ~~claims 1-8~~ wherein the R⁵ or R⁶ not selected from a group of formula (IA) is hydrogen or methylthio; or a pharmaceutically acceptable salt, ~~solvate, solvate of such a salt or a~~ prodrug thereof.

Claim 10 (currently amended): A compound of formula **(I)** according to claim 1 ~~any one of claims 1-9~~ wherein one of R^5 and R^6 is a group of formula **(IA)** ~~(as depicted above)~~;
wherein:

Z is $-O-$ or $-S(O)_b-$; wherein b is 0;

R^8 is hydrogen;

R^9 is hydrogen;

R^{10} and R^{11} are independently selected from hydrogen or carbocyclyl; wherein R^{10} and R^{11} may be independently optionally substituted on carbon by one or more substituents selected from R^{28} ;

R^{13} is a group of formula **(IB)** (as depicted above);

R^{14} is hydrogen;

R^{15} is hydrogen;

R^{17} is C_{1-10} alkyl; wherein R^{17} may be optionally substituted on carbon by one or more substituents selected from R^{47} ; or R^{17} is a group of formula **(IC)** (as depicted above) wherein:

R^{18} is selected from hydrogen;

R^{19} is selected from hydrogen;

R^{20} is C_{1-10} alkyl; wherein R^{20} may be independently optionally substituted on carbon by one or more R^{57} ;

p is 1;

q is 0;

r is 0;

m is 0;

n is 1;

z is 1; and

R^{28} , R^{47} and R^{57} are independently selected from halo and hydroxy

or a pharmaceutically acceptable salt, ~~solvate, solvate of such a salt~~ or a prodrug thereof.

Claim 11 (currently amended): A compound of formula **(I)** wherein:

M^1 is $-CH_2-$;

\mathbf{M}^2 is $-\text{CR}^{22}\text{R}^{23}-$ and $-\text{NR}^{24}-$;

\mathbf{R}^{22} and \mathbf{R}^{23} are independently selected from hydrogen and hydroxy;

~~one~~ One of \mathbf{R}^1 and \mathbf{R}^2 is ethyl and the other is butyl;

\mathbf{v} is 0;

\mathbf{R}^4 and \mathbf{R}^7 are hydrogen;

~~one~~ One of \mathbf{R}^5 or \mathbf{R}^6 is selected from a group of formula (IA) (as depicted above) and the other is hydrogen or methylthio;

\mathbf{Z} is $-\text{O}-$ or $-\text{S}(\text{O})_b-$; wherein b is 0;

\mathbf{R}^8 is hydrogen;

\mathbf{R}^9 is hydrogen;

\mathbf{R}^{10} and \mathbf{R}^{11} are independently selected from hydrogen, 2-fluorophenyl or carbocyclyl;

\mathbf{R}^{13} is a group of formula (IB) (as depicted above);

\mathbf{R}^{14} is hydrogen;

\mathbf{R}^{15} is hydrogen;

\mathbf{R}^{17} is pentyl substituted by 5 hydroxy; or \mathbf{R}^{17} is a group of formula (IC) (as depicted above) wherein:

\mathbf{R}^{18} is selected from hydrogen;

\mathbf{R}^{19} is selected from hydrogen;

\mathbf{R}^{20} is pentyl substituted by 5 hydroxy;

\mathbf{p} is 1;

\mathbf{q} is 0;

\mathbf{r} is 0;

\mathbf{m} is 0;

\mathbf{n} is 1; and

\mathbf{z} is 1;

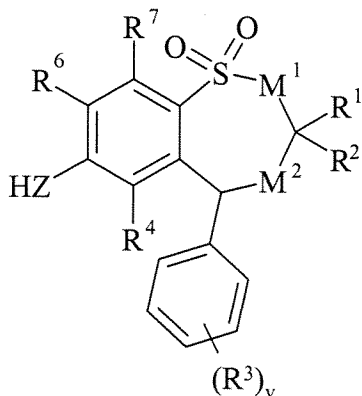
or a pharmaceutically acceptable salt, ~~solvate, solvate of such a salt or a prodrug thereof.~~

Claim 12 (currently amended): A compound of formula (I) according to claim 1 selected from:

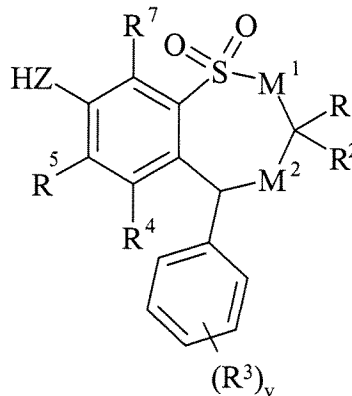
- (+/-)-trans-1,1-dioxo-3-ethyl-3-butyl-5-phenyl-7-methylthio-8-(N-{(R)- α -[N'-(2-(S)-3-(R)-4-(R)-5-(R)-2,3,4,5,6-pentahydroxyhexyl)carbamoyl]benzyl} carbamoylmethoxy)-2,3,4,5-tetrahydro-1,4-benzothiazepine;
- (+/-)-trans-1,1-dioxo-3-ethyl-3-butyl-5-phenyl-7-methylthio-8-(N-{(R)- α -[N'-(2-(S)-3-(R)-4-(R)-5-(R)-2,3,4,5,6-pentahydroxyhexyl)carbamoyl]benzyl} carbamoylmethoxy)-2,3,4,5-tetrahydro-1,4-benzothiazepine;
- 1,1-dioxo-3-ethyl-3-butyl-4-hydroxy-5-phenyl-7-(N-{ α -[N'-(2-(S)-3-(R)-4-(R)-5-(R)-2,3,4,5,6-pentahydroxyhexyl)carbamoyl]-2-fluorobenzyl} carbamoylmethylthio)-2,3,4,5-tetrahydrobenzothiepine; or
- 1,1-dioxo-3-butyl-3-ethyl-4-hydroxy-5-phenyl-7-(N-{1-[N'-(2-(S)-3-(R)-4-(R)-5-(R)-2,3,4,5,6-pentahydroxyhexyl)carbamoyl]-1-(cyclohexyl)methyl} carbamoylmethylthio)-2,3,4,5-tetrahydrobenzothiepine;
- or a pharmaceutically acceptable salt, ~~solvate, solvate of such a salt or~~ a prodrug thereof.

Claim 13 (currently amended and withdrawn): A process for preparing a compound of formula **(I)** or a pharmaceutically acceptable salt, ~~solvate, solvate of such a salt or~~ a prodrug thereof, as claimed in claim 1 ~~anyone of claims 1-12~~, which process (wherein variable groups are, unless otherwise specified, as defined in claim 1) comprises of:

Process 1): for compounds of formula **(I)** wherein Z is -O-, -NR^a or -S-; reacting a compound of formula **(IIa)** or **(IIb)**:

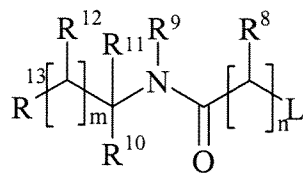


(IIa)



(IIb)

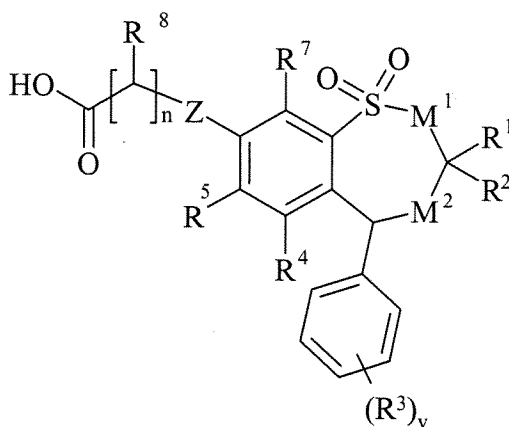
with a compound of formula **(III)**:



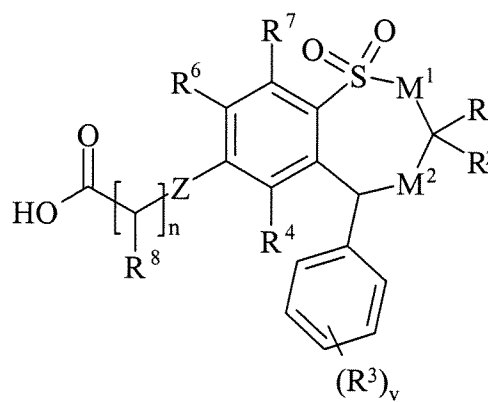
(III)

wherein L is a displaceable group;

Process 2): reacting an acid of formula **(IVa)** or **(IVb)**:

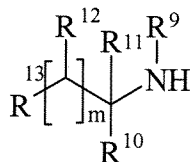


(IVa)



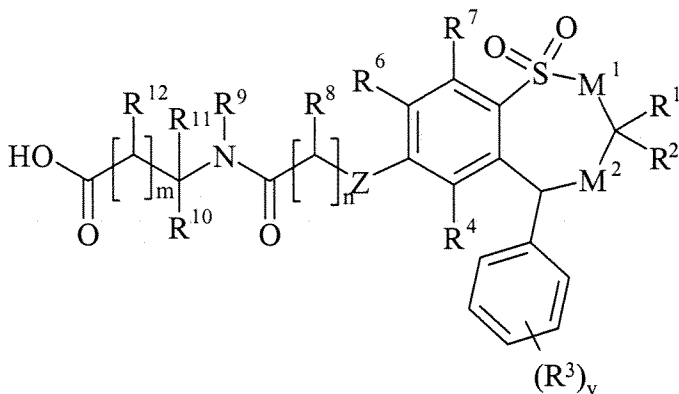
(IVb)

or an activated derivative thereof; with an amine of formula **(V)**:



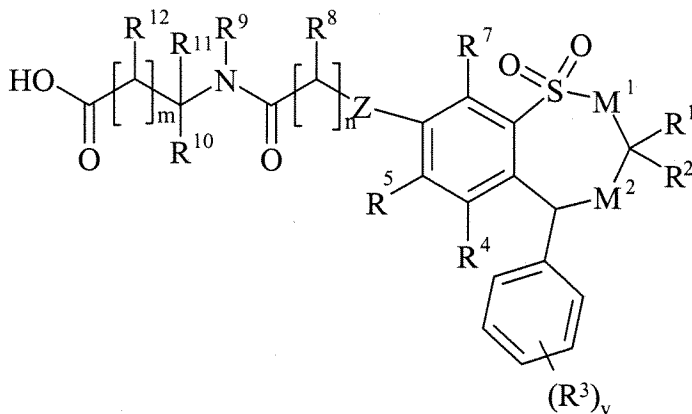
(V);

Process 3): for compounds of formula **(I)** wherein R¹³ is a group of formula **(IB)**; reacting an acid of formula **(VIa)**:



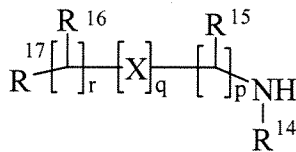
(VIa)

or (VIb):



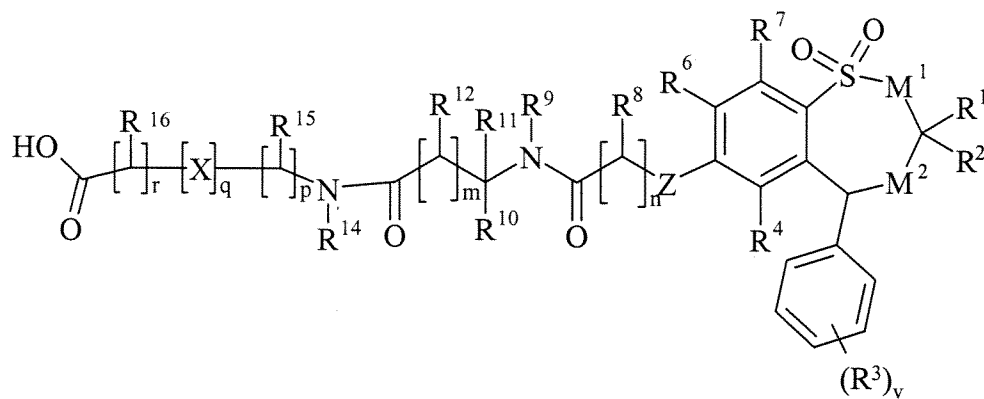
(VIb)

with an amine of formula:



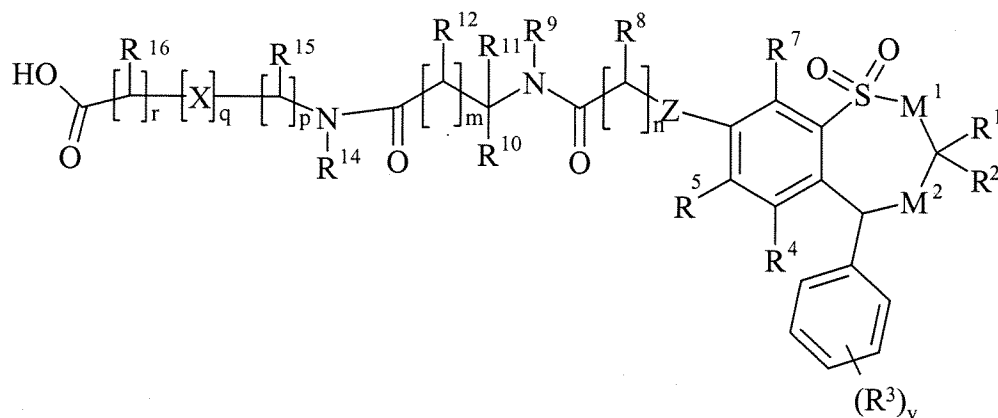
(VI)

Process 4): for compounds of formula (I) wherein R¹³ is a group of formula (IB) and R¹⁷ is a group of formula (IC); reacting an acid of formula (VIIIa):



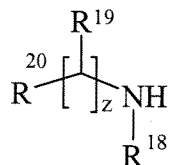
(VIIIa)

or (VIIIb)



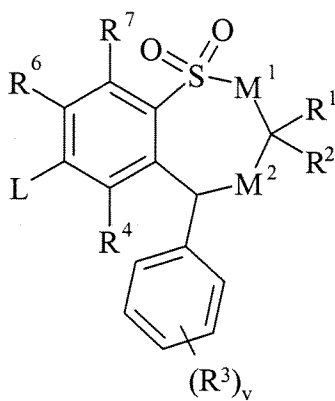
(VIIIb)

or an activated derivative thereof; with an amine of formula (IX):

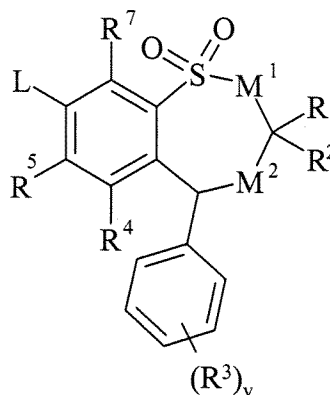


(IX)

Process 5) for compounds of formula (I) wherein one of R⁵ and R⁶ are independently selected from C₁₋₆alkylthio optionally substituted on carbon by one or more R²⁵; reacting a compound of formula (Xa) or (Xb):



(Xa)



(Xb)

wherein L is a displaceable group; with a thiol of formula (XI):



(XI)

wherein R^m is C₁₋₆alkylthio optionally substituted on carbon by one or more R²⁵;

and optionally thereafter if necessary or desirable:

- i) converting a compound of the formula (I) into another compound of the formula (I);
- ii) removing any protecting groups;
- iii) forming a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug.

Claims 14 to 16 (cancelled).

Claim 17 (currently amended and withdrawn): A method for producing an IBAT inhibitory effect in a warm-blooded animal, ~~such as man,~~ in need of such treatment which comprises administering to said animal an effective amount of a compound of formula (I), or a pharmaceutically acceptable salt, ~~solvate, solvate of such a salt~~ or a prodrug thereof, as claimed in claim 1 or claim 11 ~~any one of claims 1 to 12~~.

Claim 18 (currently amended): A pharmaceutical composition which comprises a compound of formula (I), or a pharmaceutically acceptable salt, ~~solvate, solvate of such a salt~~ or a prodrug thereof, as claimed in claim 1 or claim 11 ~~any one of claims 1 to 12~~, in association with a

pharmaceutically-acceptable diluent or carrier.

Claims 19 to 25 (cancelled).